DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Dornier MedTech America, Inc.
% Mr. John Hoffer
Vice President, Quality/Regulatory/Clinical
1155 Roberts Blvd.
KENNESAW GA 30144

November 26, 2014

Re: K133434
Trade/Device Name: Genesis II
Regulation Number: 21 CFR 892.1650
Regulation Name: Image intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: JAA
Dated: October 23, 2014
Received: October 23, 2014

Dear Mr. Hoffer:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133434

Device Name

Genesis II

Indications for Use *(Describe)*

The Dornier GENESIS II is intended for use in a wide field of applications, including all general examinations in urology and gynecology, as well as endoscopic and contrast examinations, imaging with radiography and/or fluoroscopy on patients in either the horizontal or vertical position.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Dornier MedTech America, Inc.'s
Genesis II

Sponsor Company:	Dornier MedTech America, Inc.
Sponsor Address:	1155 Roberts Blvd. Kennesaw, GA 30144
Contact Person:	John Hoffer Vice President, Quality/Regulatory/Clinical
Email Address:	jhoffer@dornier.com
Phone Number:	770-514-6163
Fax Number:	770-514-6291
Date Prepared:	October 23, 2014
Device Trade Name(s):	Genesis II
Device Common Name:	Image Intensified Fluoroscopic X-ray System
Classification Name	(21 CFR 892.1650, Product Code JAA)
Predicate Device(s):	Dornier Genesis (K122768) Dornier Gemini (K121656) Dornier Urotract (K955019)

General Device Description:

The Dornier Genesis II is an Image Intensified Fluoroscopic X-ray System. It is intended for use in a wide field of applications, including all general examinations in urology and gynecology, as well as endoscopic and contrast examinations, imaging with radiography and/or fluoroscopy on patients in either the horizontal or vertical position.

The Genesis II consists of the following components: an x-ray generator and tube housing, image intensifier detector, monitors and procedure table. An X-ray cabinet contains system elements such as the X-ray generator, power electronics and electronics for the imaging chain.

The Genesis II is a radiographic and fluoroscopy examination table with the X-ray tube housing mounted over the table on a fixed arm. An image intensifier is mounted underneath the patient table. While the X-ray tube and detector are fixed in their positions relative to each other when the system is in use, the table top and X-ray/detector unit can be moved in a variety of planes to position the patient in the desired imaging position.

Indications For Use:

> The Dornier GENESIS II is intended for use in a wide field of applications, including all general examinations in urology and gynecology, as well as endoscopic and contrast examinations, imaging with radiography and/or fluoroscopy on patients in either the horizontal or vertical position.

Genesis II has the same intended use and indications for use as the predicate Genesis system (K122768).

Comparison of Technological Characteristics:

The Genesis II is an Image Intensified Fluoroscopic X-ray System with an image intensifier image receptor system. Both the Genesis II and the predicate Genesis (K122768) consist of the following components: an X-ray generator and tube housing, image intensifier, monitors and procedure table. The X-ray cabinet contains system elements such as the X-ray generator, power electronics and electronics for the imaging chain.

The only technological difference between the Genesis II and the predicate Genesis (K122768) is the substitution of an Image Intensifier for the predicate device's Flat Panel Detector. The image intensifier system in the Genesis II is identical to the solid state image intensifier system used in the Dornier Gemini Lithotripter system (K121656). Both imaging systems have demonstrated the ability to provide acceptable image quality appropriate for the intended uses of the device. Furthermore, the use of image intensifiers with uroradiology systems with substantially similar indications for use as those of the Genesis II have been previously cleared by FDA (e.g., Urotract I (K955019)). Therefore, the use of cleared image intensifier technology in the Genesis II does not raise any new questions of safety or effectiveness and meets the requirements for substantial equivalence.

Non-Clinical Performance Data:

The device is in compliance with the following consensus standards:

- IEC 60601-1: Medical electrical equipment. Part 1: General requirements for safety (2005)
- IEC 60601-1-2: Medical electrical equipment. Part 1-2: General requirements for safety; Electromagnetic compatibility-requirements and tests (2007)
- IEC 60601-1-3: Medical electrical equipment. Part 1: General requirements for safety; general requirements for radiation protection in diagnostic X-ray equipment (2008)
- IEC 60601-1-6: Medical electrical equipment. Part 1-6: General requirements for basic safety and essential performance -Collateral standard: Usability (2006)
- IEC 60601-2-28: Medical electrical equipment. Part 2: Particular requirements for the safety of X-ray source assemblies and X-ray tube assemblies for medical diagnosis (2010)
- IEC 60601-2-54: Medical electrical equipment. Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy (2009)
- NEMA PS 3.1-3.20 – Digital Imaging and Communications in Medicine (DICOM) Set

To verify and validate diagnostic quality of the device output image, a board certified radiologist evaluated a number of sample images obtained using the Genesis II and determined that the device output images were of acceptable diagnostic quality and that the performance of the proposed device is substantially equivalent to that of the cleared Genesis (K122768).

Conclusion and Summary of Substantial Equivalence:

Genesis II has the same intended use and indications for use as the previously cleared Genesis system (K122768). The only technological difference between the Genesis II and the predicate Genesis system is the substitution of an Image Intensifier for the predicate device's Flat Panel Detector. The image intensifier system in the Genesis II is identical to the solid state image intensifier system used in the Dornier Gemini Lithotripter system. The Genesis II has demonstrated the ability to provide acceptable image quality appropriate for the intended uses of the device. Based on intended use, technological characteristics, and performance data as discussed above, Dornier believes that the Genesis II and the predicate devices selected are substantially equivalent and that the differences between the devices do not raise new issues of safety or effectiveness.